K033544

DEC 1 0 2003

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Everyway Medical Instruments Co., Ltd
2-Address: 3FL., No.5, LANE 155, Sec. 3, Peishen Rd
Shen Keng Hsiang. Taipei Hsien. Taiwan (ROC)
3-Phone: (886) 2 2662 0038
4-Fax: (886) 2 2664 5566
5-Contact Person: Mr Robert Tu (General Manager)
6-Date summary prepared: November 3rd, 2003
7- Official Correspondent: Mansour Consulting LLC
8- Address: 1308 Morningside Park Dr. Alpharetta, GA 30022 USA
9- Phone: 770-777-4146
10- Fax: 678-623-3765
11- Contact Person: Jay Mansour, President
12-Device Trade or Proprietary Name: Electrical Muscle Stimulator
13-Device Common or usual name: EMS
14-Device Classification Name: Stimulator, muscle, powered
15-Substantial Equivalency is claimed against the following device:

- Digital EMS, model EV-807 from Everyway Medical Instruments Co., Ltd. 510k# K020750

16-Description of the Device:

The Special 510(k) premarket notification describes a modification to Everyway's currently legally marketed EV-807 Digital Electrical Stimulator. The proposed modifications include technical specifications (Output amplitude, range of pulse width, pulse rate, ramp time), buttons to adjust parameters and shape unit. Basically the change is from digital version to analogue version of EMS. The specifications of units are modified according to the requirements of customers while are still very similar to the predicated unit.

The intended use of the modified devices is the same as for the predicate device. In addition, the scientific technology, manufacturing methods, and operating principles for the changed devices are equivalent to those of the predicate device.

17-Intended use of the device: (refer to FDA form attached)

Electrical Muscle Stimulator Series (Model Numbers N605, N607) is an electrically powered muscle stimulator intended for use for medical purposes to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular, this device is indicated for use for:

- Relaxing muscle spasms
- Increasing local blood circulation.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Muscle re-education.
- Maintaining or increasing range of motion
- Preventing or retarding disuse atrophy

18-Safety and Effectiveness of the device:

This device is safe and effective as the predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K020750
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Not Applicable
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Not Applicable
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical
Thermal safety	Identical
Radiation safety	Not Applicable

Refer to the submission for more details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2003

Everyway Medical Instruments Co., Ltd.
C/o Mr. Jay Mansour, MSQA, BE, LA, RAC
President
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K033544
Trade/Device Name: Electrical Muscle Stimulator, Models N605 and N607
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: November 3, 2003
Received: November 10, 2003

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033544

Device Name: ELECTRICAL MUSCLE STIMULATOR – MODELS N605 & N607

Indications For Use:

ELECTRICAL MUSCLE STIMULATOR SERIES IS AN ELECTRICALLY POWERED MUSCLE STIMULATOR INTENDED FOR USE FOR MEDICAL PURPOSES TO REPEATEDLY CONTRACT MUSCLES BY PASSING ELECTRICAL CURRENTS THROUGH ELECTRODES CONTACTING THE AFFECTED BODY AREA.

IN PARTICULAR, THIS DEVICE IS INDICATED FOR USE FOR:

- RELAXING MUSCLE SPASMS
- INCREASING LOCAL BLOOD CIRCULATION
- IMMEDIATE POST-SURGICAL STIMULATION OF CALF MUSCLES TO PREVENT THROMBOSIS
- MUSCLE RE-EDUCATION
- MAINTAINING OR INCREASING RANGE OF MOTION
- PREVENTING OR RETARDING DISUSE ATROPHY

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K033544